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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/486,392 06/15/00 KIM

H 012679-066

021839 HM12/1101
BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA VA 22313-1404

EXAMINER

FOLEY, S

ART UNIT	PAPER NUMBER
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1648 *6*

DATE MAILED:

11/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/486,392	KIM ET AL.
	Examiner Shanon A. Foley	Art Unit 1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - a) All b) Some * c) None of the CERTIFIED copies of the priority documents have been:
 1. received.
 2. received in Application No. (Series Code / Serial Number) _____.
 3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	20) <input type="checkbox"/> Other: _____

DETAILED ACTION

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Objections

Applicant is advised that should claim 3 be found allowable, claim 8 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that CJ50003 is required to practice the claimed invention in order to obtain the properties of multiplicity of 1x10(7) PFU/ml in Vero cells and the lethal dose in a young mouse less than 0.000001. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the Japanese encephalitis virus. See 37 CFR 1.802.

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The specification does not provide a repeatable method for obtaining a virus cultured in Vero cells with the desired properties described in claim 2 and it is not apparent if it is readily to the public. Applicant's deposit statement on specificaiton page 5 does not indicate the extent of public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6, 7, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Huiying et al.

The claims are drawn to an attenuated Japanese encephalitis virus vaccine adapted to Vero cells that is untreated by an inactivating agent in a pharmaceutically acceptable carrier.

Huiying et al. teaches a Japanese encephalitis virus that has been adapted in Vero cells. This method of virus propagation is proposed for vaccine production to avoid the possible contamination of extraneous agents compared with using the virus from the mouse brain, see the abstract. Huiying et al. does not teach inactivation of the virus by any chemical means. Since claims 4, 6, 7, and 10 require only virus and carrier, the reference virus composition meets these claim limitations. In addition, a vaccine by definition is administered to an organism for the prevention and/or treatment of an infectious disease and therefore, by definition is contained in a pharmaceutically acceptable carrier.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huiying et al. and Barret.

The claims are drawn to an inactivated Japanese encephalitis virus vaccine that grown on Vero cells in a pharmaceutically acceptable carrier.

See the teachings of Huiying et al. above. Huiying et al. does not teach a virus that has been inactivated by an inactivating agent.

Barret et al. teaches the Nakayama formalin-inactivated Japanese encephalitis vaccine that have been commercially available since 1973 that was grown in mouse brain. Another formalin-inactivated Japanese encephalitis virus vaccine commercially available since 1968 is the Peking 3 grown in primary hamster kidney cells. The immunity of these vaccines are short-lived and subsequent booster shots are necessary, see "Inactivated vaccines" and "Immunization regimen and seroconversion" on pages 27-28. Barret does not teach a Japanese encephalitis virus that has adapted to Vero cells.

One of ordinary skill in the art at the time the invention was made would have been motivated to inactivate an attenuated Japanese encephalitis virus in Vero cells taught by Huiying et al. to protect people who are immunocompetent. From the teaching of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success

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in producing the claimed invention because of inherent low virulence of the inactivated vaccines taught by Barret above that require extensive boosters of the vaccine to maintain an immune response. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made as evidenced by the references.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 7:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
October 23, 2000

MARY E. MOSHER
PRIMARY EXAMINER
~~GROUP 1000~~

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